

**REMARKS**

Claims 2-18 remain pending in this application. Claims 10 and 15 have been amended for clarification and not for reasons of patentability. These amendments in no way narrow the scope of the claims.

**Objection under 37 C.F.R. 1.75(c)**

Claims 2-4 were objected to under 37 C.F.R. 1.75(c), for failing to further limit the subject matter of a previous claim. However, 37 C.F.R. 1.75(c) requires that each dependent claim further limit the subject matter of "another" claim in the same application. Claims 2, 3 and 4 further limit claim 5, from which they depend, by further defining the applying agent claimed in claim 5. Furthermore, the scope of claims 2, 3 and 4 are distinct in that they place differing limitations on the scope of the claimed applying agent. As a result, claims 2, 3, and 4 further limit the subject matter of another claim in the application as required by 37 C.F.R. 1.75(c). It is Applicant's understanding that upon allowance, claims 2-4 will be renumbered consecutively, beginning with the number next following the highest numbered claim previously presented, in accordance with MPEP 1302.01. Because the objection under 37 C.F.R. 1.75(c) was the only objection to claims 2-4 and these claims are in proper dependent form, Applicant submits that claims 2-4 are in condition for allowance.

**Rejection under 35 U.S.C. §§ 102 and 103**

Claims 5-18 were rejected under 35 U.S.C. § 102 and/or 103 as being anticipated and/or obvious over Green et al. However, because Green et al. does not disclose the combination of ingredients claimed in claims 5-9, or the combination of treatment steps claimed in claims 12, 14 or 16, it cannot anticipate such claims. Furthermore, nothing in Green et al. teaches or suggests

the combination of ingredients claimed in claims 5-9 or the combination of steps claimed in claims 10-18. As a result, a *prima facie* case of obviousness for rejecting claims 2-18 has not been established.

Rejection of claims 5-9

Applicant submits that claims 5-9, 12, 14 and 16 are not anticipated by Green et al. In order for a reference to anticipate a claim, the identical invention must be disclosed in a single prior art reference. See Minnesota Mining & Manufacturing Co. v. Johnson & Johnson Orthopaedics, Inc., 1565, 24 U.S.P.Q.2d 1321, 1326 (Fed. Cir. 1992) ("A party asserting that a patent claim is anticipated under 35 U.S.C. 102 must demonstrate, among other things, identity of invention.") Green et al. simply does not disclose the combination of ingredients and steps required by the claims at issue.

Independent claim 5 covers a topical nail formulation, comprising the mixture of: calcium hydroxide, sodium hydroxide, an antifungal agent and an applying agent, wherein the calcium hydroxide and sodium hydroxide are present in the formulation in a ratio of about 40:60 to 60:40 by weight. Independent claim 6 is similar, requiring the same combination of ingredients and specifying the relative weight percentages of the ingredients in the formulation. Independent claim 9 requires the same combination of ingredients, with the addition of an antibiotic. These claims, and the claims which depend therefrom, are not anticipated by Green et al. because (i) at least one of the ingredients is not disclosed in Green et al.; (ii) the combination of ingredients is not disclosed in Green et al.; and (iii) the specific ratios and weight percentages required by the claims are not disclosed in Green et al.

More specifically, Green et al. does not disclose the use of an antifungal agent. Green et al. does disclose the optional use of "antimicrobial agents." However, "antimicrobial agents" include a broad spectrum of substances. Green et al. mentions a few such substances, namely, "antibiotics, anesthetics, analgesics and antipuritic agents." However, Green et al. does not specifically disclose the use of antifungal agents. A prior genus which does not explicitly disclose a species does not anticipate a later claim to that species. In re Meyer, 202 U.S.P.Q. 175 (C.C.P.A. 1979) ("The genus, 'Alkaline chlorine or bromine solution,' does not identically disclose or describe, within the meaning of § 102, the species alkali metal hypochlorite"). Thus, Green et al.'s broad disclosure of "antimicrobial agents" does not disclose the claimed "antifungal agent" within the meaning of § 102. Green et al. cannot, therefore, anticipate independent claims 5, 6 or 9, which require an antifungal agent, or claims 7 and 8, which depend therefrom.

Further, Green et al. does not disclose the combination of ingredients required by claims 5, 6 and 9. Green et al. discloses the optional use of various bases and acids to form pharmaceutically acceptable salts with the compounds of the Green et al. invention. Among the suitable bases disclosed are sodium hydroxide, sodium carbonate, sodium bicarbonate, potassium hydroxide, calcium hydroxide, ammonia and amines. Green et al. in no way discloses combining two such bases in a single composition and in no way discloses specifically combining sodium hydroxide and calcium hydroxide in a single composition as required for anticipation. Similarly, Green et al. in no way discloses the combination of two or more antimicrobial agents and in no way discloses the specific combination of an antifungal agent and an antibiotic, as required by claim 9.

Nor does Green et al. specifically disclose the combination of sodium hydroxide and/or calcium hydroxide with an antifungal agent and an applying agent. Even if disclosure of an antimicrobial were sufficient to disclose an antifungal agent for purposes of anticipation, a large number of optional ingredients are disclosed in Green et al. There is simply no disclosure of the specific combination of sodium hydroxide, calcium hydroxide, an antifungal agent and an applying agent out of all of the ingredients disclosed in Green et al.

Finally, nothing in Green et al. discloses the specific ratios and percentages required by claims 5, 6, 7, and 8. In fact, because Green et al. does not disclose the combination of ingredients required by the claims, it cannot disclose the ratios and percentages required by the claims. As a result, independent claims 5 and 6, and claims 7 and 8, which depend therefrom, are not anticipated by Green et al.

Independent claim 12, and claims 14 and 16 which depend therefrom, also have been rejected under 35 U.S.C. § 102 over Green et al. Claim 12 is directed to a method for treating a nail of a patient, comprising: providing a formulation comprised of a mixture of calcium hydroxide, sodium hydroxide, an antifungal agent and an applying agent; and applying the formulation to a nail of a patient in need thereof. As discussed above, Green et al. does not disclose the formulation used in the claimed method. As a result, Green et al. does not anticipate the claimed method. Furthermore, Green et al. does not disclose the step of applying its formulation to the nail of patient, thus providing a further reason that independent claim 12 is not anticipated by Green et al.

With respect to dependent claims 14 and 16, Green et al. does not disclose applying the formulation to a nail having a specific thickness and Green et al. does not disclose the step of

applying an emollient to skin surrounding the nail. This provides additional reasons that dependent claims 14 and 16 are not anticipated by Green et al.

Based on the foregoing, Applicant submits that claims 12, 14 and 16 are not anticipated by Green et al. and respectfully requests removal of the rejection of such claims under 35 U.S.C. § 102.

Rejection under § 103: Claims 5-18

Applicant submits that a *prima facie* case of obvious has not been made with respect to claims 5-18. There is simply no teaching or suggestion in Green et al. to combine the specific ingredients required by claims 5-9 or to perform the specific steps required by claims 10-18. The Patent and Trademark Office's burden of establishing a *prima facie* case of obviousness is not met unless "the teachings from the prior art itself would appear to have suggested the claimed subject matter to a person of ordinary skill in the art." In re Bell, 26 U.S.P.Q.2d 1529, 1531 (Fed. Cir. 1993)(quoting In re Rinehart, 189 U.S.P.Q. 143, 147 (C.C.P.A. 1976)). Not only does Green et al. not suggest all of the individual elements of the pending claims, it does not suggest selecting and combining the claimed elements from the vast number of possible ingredients and combinations disclosed. Still further, Green et al. provides no motivation to make a formulation for treating fungus under one's nail. Thus, a *prima facie* case of obviousness has not been established with respect to the present claims.

Green et al. is directed to specific novel compounds useful in treating hyperproliferative diseases, such as psoriasis. Green et al. discloses a wide variety of components that can be added to the novel compounds to form formulations for treating hyperproliferative disease. Green et al. also discloses the application of formulations comprising the novel compounds to skin affected

by the hyperproliferative disease. Green et al. is not concerned with treating toenails, fingernails or fungal conditions.

Green et al. does not teach or suggest a formulation containing both sodium hydroxide and calcium hydroxide, as claimed by Applicant. As noted above, Green et al. discloses a broad genus of bases and acids that can be combined with its novel compound to form salts. Sodium hydroxide and calcium hydroxide are just two of many bases suggested. However, there is no suggestion in Green et al. to combine two separate bases. In fact, there would be no need to combine two separate bases to form a salt. None of the exemplified formulations of Green et al. contains more than one of the suggested bases. Even if one were motivated to combine bases, which Applicant does not believe is the case, there is simply no suggestion to combine sodium hydroxide and calcium hydroxide out of the broad genus of bases disclosed by Green et al.

Furthermore, the combination of sodium hydroxide and calcium hydroxide provide important benefits not suggested by Green et al. and not apparent to one of ordinary skill in the art. Applicant's composition is designed to treat nails. In order for the antifungal agent of Applicant's invention to treat fungus beneath nails, it must penetrate the nail. Conventional formulations for skin treatment are not able to penetrate toenails and fingernails. Surprisingly, Applicant has found that the combination of sodium hydroxide and calcium hydroxide provides a dual delivery system that will penetrate the nail to deliver an antifungal agent. Such a purpose is in no way suggested or disclosed by Green et al. and nothing in Green et al. would motivate one of ordinary skill in the art to develop such a dual delivery system.

In addition, there is no suggestion in Green et al. to add an antifungal agent to the formulation of Green et al. or to a dual delivery systems comprising sodium hydroxide and

calcium hydroxide. As noted above, Green et al. discloses a broad genus of antimicrobial agents and several specific agents. Green et al. does not disclose use of antifungal agents and does not suggest that the antimicrobial agent should have antifungal properties.

The mere mention of optionally adding antimicrobial agents, which cover a large genus of compounds, does not make a formulation containing a particular unnamed species within that genus, namely an antifungal agent, obvious, especially when the species is used in a different formulation for an entirely different application. See In re Jones, 21 U.S.P.Q.2d 1941, 1943 (Fed. Cir. 1992), (Cited reference discloses "the potentially infinite genus of substituted ammonium salts of dicamba, and lists several such salts", but the salt claimed by the Applicant is not specifically disclosed. The Court reasoned that the claimed salt was not sufficiently similar in structure to those specifically disclosed in the cited reference as to render it *prima facie* obvious.) Green et al. is concerned with treating hyperproliferative diseases, not fungal conditions. There is no suggestion in Green et al. of a need to kill fungus or a particular suggestion of using an antifungal agent. Furthermore, Green et al. specifically points to certain other antimicrobial agents that would be useful. Based on the teachings of Green et al., there simply would be no motivation for one of ordinary skill in the art to select an antifungal agent from the broad genus of antimicrobial agents disclosed by Green et al.

Furthermore, there is nothing in Green et al. to suggest the specific combination of ingredients claimed by Applicant. Green et al. discloses a novel compound and a large number of optional components to add to a formulation containing the novel compound. There is simply no suggestion to pick and choose from the many components contained in the disclosure of Green et al. to arrive at the combination covered by the present claims. This is particularly true in view of Green et al.'s failure to suggest the use of more than one base or use an antifungal

agent. Applicant's combination of ingredients is not simply a matter of design choice. Rather, Applicant has found this combination to be surprisingly effective in delivering antifungal agents to nails, a purpose with which Green et al. was in no way concerned.

Finally, because there is no suggestion in Green et al. to use the specific ingredients required by claims 5 and 6, there is certainly no suggestion to use the ingredients in the ratio and percentages required by claims 5, 6, 7 and 8. This provides yet one more reason that claims 5-8 are not rendered obvious by Green et al.

Independent claim 10, and claim 11, which depends therefrom, are directed to a method of making a topical nail formulation comprising calcium hydroxide, sodium hydroxide, an antifungal agent and an applying agent. Because there is no suggestion in Green et al. to make such a formation, there is likewise no suggestion in Green et al. to combine such ingredients as required by claims 10 and 11. As a result, claims 10 and 11 are not rendered obvious by Green et al.

Independent claim 12 and claims 13-16 which depend therefrom are directed to a method for treating a nail of a patient. Again, because there is no suggestion in Green et al. to combine the specific ingredients listed in the claim, there would be no suggestion to provide such a formulation.

In addition, there is no suggestion in Green et al. to apply its formulation to a nail of a patient as required by claim 12. As discussed above, Green et al. is concerned with treatment of hyperproliferative skin disorders such as psoriasis. Green et al. discloses applying its formulation to the skin affected by such disorder. There is no suggestion in Green et al. to apply its formulation to nail, insofar as Green et al. was concerned with treating diseases of the skin.



Application of a formulation directly to the skin is very different than application of a formulation to a nail. In order to treat a condition, such as a fungus, under the nail, the formulation must actually penetrate the nail. Conventional formulations used for skin treatments do not penetrate the nail. One of ordinary skill in the art would have no expectation that the formulation of Green et al. would be effective when applied to a nail. In fact, Green et al.'s formulation would not work to treat one's nails because it does not contain the dual component penetration system of calcium hydroxide and sodium hydroxide found by Applicant to penetrate nails. Furthermore, Green et al. provides no teaching or suggestion that an antifungal agent placed in a calcium hydroxide and sodium hydroxide system would be effective for such purpose. Thus, one of ordinary skill in the art would find no motivation in Green et al. to apply its formulation to a nail.

In addition, Green et al. in no way teaches or suggests the limitations in dependent claims 13 through 16. For example, claim 15 requires application of the claimed formulation to a nail having a fungal infection. Nothing in Green et al., which is concerned with treatment of psoriasis and similar diseases, suggests a method in which its formulation or any other would be applied to a nail having a fungal infection. These additional limitations, which are not suggested by Green et al., provide additional reasons such claims are not obvious over Green et al.

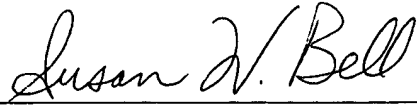
### **Conclusion**

In view of the foregoing amendments and remarks, it is respectfully submitted that the claims are now in condition for allowance and eventual issuance. Such action is respectfully requested. Should the Examiner have any further questions or comments which need be

addressed in order to obtain allowance, please contact the undersigned attorney at the number listed below.

Acknowledgement of receipt is respectfully requested.

Respectfully submitted,

By:   
Susan Wharton Bell, Reg. No. 41,524  
STINSON MORRISON HECKER LLP  
1201 Walnut, Suite 2800  
Kansas City, MO 64106-2150  
Telephone: (816) 842-8600  
Facsimile: (816) 691-3495